

### REMARKS

Claims 1-4, as amended, and new claim 11 appear in this application for the Examiner's review and consideration. Claims 5 and 6 were cancelled without prejudice. Applicants reserve the right to pursue the subject matter of claims 5 and 6 in a continuation, divisional, or continuation-in-part application. Claims 7-10 were withdrawn by the examiner as directed to non-elected subject matter.

Claims 1-6 stand rejected under 35 U.S.C. § 101 for the reasons set forth on page 2 of the Office Action. Applicants respectfully traverse.

In order to satisfy the utility requirement of 35 U.S.C. § 101, the disclosures of an application must "establish a specific and substantial utility for the claimed invention." *See In re Fischer*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). To meet the "specific" utility requirement, an application must disclose a use "which is not so vague as to be meaningless." *See id.* In order to satisfy the "substantial" utility requirement, the disclosure "must show that the claimed invention has a significant and presently available benefit to the public." *See id.*

Azithromycin as well as by-products in its synthesis may degrade to form degradation products. Therefore, a person of skill in the art seeking to determine the purity of a sample of azithromycin, would not be able to predict which of the myriad of possible contaminants would be useful as a reference marker for detecting degradants. The identification of specific degradation products and their use as reference markers present in a particular sample of azithromycin clearly has utility because this information could be used, for example, to determine optimum storage conditions that would minimize degradation of the azithromycin.

Both requirements of "specific" and "substantial" utility are met by the disclosure. In the "Field of the Invention" the application states that "[t]he invention encompasses the degradation products of azithromycin, ... to methods of identifying such degradation products" and "the compounds [are] useful as reference markers for the analysis of azithromycin and pharmaceutical formulations thereof." Application p. 1, ll. 8-12.

Thus, the disclosure sets forth a specific utility requirement for the compounds and methods of identifying degradation products. Furthermore, the disclosure teaches how to use the degradation products as markers in compositions for qualitative and quantitative analysis. Such that the requirements for utility are met by using these compounds to identify impurities within azithromycin and quantification of them when using the compounds as an internal. Consequently, the rejection under 35 U.S.C. § 101 cannot stand and should be withdrawn.

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse.

The Office Action asserts "the claimed invention is not supported by either a specific asserted utility or a well established utility asserted utility or a well established utility." Office Action of September 27, 2006, p. 3. However, as applicants have explained above, the utility requirement has been met. Consequently, any enablement rejection based upon the utility rejection is as well overcome. Accordingly, the rejection of claims 1-6 under 35 U.S.C. § 101 112, first paragraph cannot stand and should be withdrawn.

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. patent No. 4,474,768 to Bright *et al.* ("the '768 patent") for the reasons set forth at pages 3 and 4 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art, and must disclose every element of the challenged claim. *Motorola Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997); *PPG Industries Inc. v. Guardian Industries Corp.*, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 U.S.P.Q. 160 (Fed. Cir. 1986). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An anticipatory reference must also enable one of ordinary skill in the art as to the claimed subject matter.

Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that is would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002).

The Office Action fails to establish an anticipatory rejection because the Office Action fails to present any argument to substantiate that the missing element is necessarily present in the '768 patent or that the compounds would be so recognized by persons of ordinary skill in the art within the '768 patent. In fact, the reasoning for the anticipatory rejection and obviousness rejection is so sparse, that applicants have reproduced it below:

Bright discloses a pharmaceutical composition comprising azithromycin (column 7, lines 23-54). The claimed degradation products are inherently contained in the compositions disclosed by Bright.

The Office Action p. 4.

In these 24 words, the Office Action contends that a legally sufficient basis for establishing a *prima facie* case for anticipation AND obviousness has been made. For the reasons discussed herein, applicants contend that the legal standard for establishing either anticipation or obviousness has not been met.

The '768 patent does not recite each and every element of claims 1-6. Compounds II and III (including III-a) of the '768 patent have an oxidized tertiary amine at the 3' position of the pyran ring and an oxidized amine at the 11 position. In contrast, the compounds of the claims do not have an oxidized amine at the 11 position. Furthermore, the '768 patent does not disclose compounds of the claims having either an N-aldehyde or a ketone on the pyran ring.

The recited compounds are not inherent in the '768 patent, as the Office Action fails to set forth any reasoned basis to establish that the missing element is necessarily present. Applicants remind the Office that specificity is important and that the missing element is not established by mere probability or possibility of its presence in the prior art.

Accordingly, the rejection of claims 1-6 under 35 U.S.C. § 102(b) as anticipated by '768 patent cannot stand and should be withdrawn.

Claims 1-6 stand rejected under 35 U.S.C. § 103(a) as rendered obvious over the '768 patent for the reasons set forth on pages 3 and 4 of the Office Action. Applicants respectfully traverse.

The consistent criterion for determination of obviousness is whether the prior art would have suggest to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). As the Examiner is well aware, in order to form a proper basis for a rejection under 35 U.S.C. § 103, the prior art must provide

some suggestion, either explicit or implicit, of the combination that allegedly renders a claimed invention obvious. *M.P.E.P.*, § 2142 (June 1998), *see also*, *Panduit Corp. v. Denisson Manufacturing Co.*, 1 U.S.P.Q.2d 1593, 1597 (Fed. Cir. 1987). The Examiner can satisfy the burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Sang Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002); citing *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The need for specificity is paramount, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected the components for combination in the manner claimed. *Id.* The Examiner's conclusory statements do not adequately address the issue of motivation to combine; the factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. *Id.*

The lack of specificity in the rejection, as reproduced above, fails to meet the legal requirements for establishing a *prima facie* case of obviousness. The Office Action has failed to determine the scope and content of the prior art; ascertain the differences between the prior art and the claims in issue; and determine the level of ordinary skill in the art. Absent these basic considerations as required by the Supreme Court in *Graham v. Deere* the Office Action cannot determine whether the claims lack patentability under § 103. *See Graham v. John Deere*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966).

Moreover, the Office Action does not show or explain some objective teaching in the prior art or knowledge generally available to one of ordinary skill in the art that would lead the individual to the subject matter of the recited claims. As explained above, specificity is paramount, and particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have obtained the recited subject matter. Without this legal analysis, applicants cannot respond to the rejection as the reason for establishing obviousness is unknown to them.

Lastly, applicants remind the Office that conclusory statements do not adequately address the issue of motivation to combine; the factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority.

Accordingly, the rejection of claims 1-6 under 35 U.S.C. § 103(a) as rendered obvious by the '768 patent cannot stand and should be withdrawn.

Accordingly, it is believed that claims 1-6 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. ~~11~~-0600.

Respectfully submitted,

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